



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: Review of product chemistry, manufacturing process, and waiver requests for acute toxicities studies of the end use product Summit B.t.i. Briquets (EPA Reg. No. 6218-IT) containing the active ingredient *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218

FROM: Ibrahim S. Barsoum, Ph.D., Microbiologist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

Ibrahim S. Barsoum 11/2/16

THROUGH: John L. Kough, Ph.D., Senior Scientist
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

John L. Kough 11/2/16

TO: Jennifer Wingert, Regulatory Action Leader
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

ACTION REQUESTED: To review product chemistry, manufacturing process data, waiver requests for acute toxicities studies, and product performance of the end use product Summit B.t.i. Briquets (EPA Reg. No. 6218-IT) containing the active ingredient *Bacillus thuringiensis* subsp. *israelensis* strain SUM 6218 for section 3 registration of the product.

CONCLUSION: **UPGRADABLE** pending on the registrant addressing the following issues:

- 1) Remove all food-use applications of the product from label.
- 2) A one-year study of storage stability and corrosion characteristics should be submitted upon completion.

DATA REVIEW RECORD

Active Ingredients: *Bacillus thuringiensis israelensis* strain SUM 6218
Product Name: Summit B.t.i. Briquets
Company Name: Summit Chemical Co.
ID No: 6218- IT
Chemical Numbers: 006642
Submission Number: 978993
DP Barcode: 431321
MRID No: 497999-02 - 09 Product Chemistry for Summit B.t.i. Briquets
497999-10 - 15 Waiver Requests for Acute Toxicities Studies

BACKGROUND:

Summit B.t.i. Briquets is an end use product to be used to control mosquito larvae in a variety of water habitats including natural and manmade sites where mosquitoes may develop. The active ingredient is 10.31% w/w *Bacillus thuringiensis* subspecies *israelensis*, strain SUM-6218, supplied by SUM-6218 Primary Powder (7000 ITU/mg, EPA Reg. No. 6218-83).

DISCUSSION:

Migration of impurities into the product is unlikely. Post-product reactions, including the migration of impurities from the packaging, are also unlikely. The low acute toxicity of the active ingredient, the known low toxicity of the inert ingredients that are exempt from tolerance, and the low concentrations of a cross linking agent and a sunscreen in Summit B.t.i. Briquets supports the position that an acute toxicity studies in laboratory animals are not necessary to support registration of Summit B.t.i. Briquets. However, the Agency requires to incorporate the proposed bioassay of the EP beside the bioassay of the A.I. and to change the potency of the EP on the label to 721.7 ITU. Also, all food-use applications should be removed from the label.

RECOMMENDATION:

UPGRADABLE pending on the registrant addressing the following issues:

- 1) Incorporate bioassay of the EP beside bioassay of the TGAI.
- 2) Change the potency of the EP to 721.7 ITU on the label.
- 3) Remove all food-use applications of the product from label.
- 4) A one-year study of storage stability and corrosion characteristics should be submitted upon completion.

SUMMARY OF DATA SUBMITTED:

Product Characterization & Manufacturing Process

Product Identity:

Product Name: Summit B.t.i. Briquets

Active Ingredient(s): *Bacillus thuringiensis* subspecies *israelensis* Strain SUM 6218 solids, spores and insecticidal toxins

Nominal Concentration: 10.31%

Certified Limits: Upper Limit [REDACTED], Lower Limit [REDACTED]

Active ingredient: *Bacillus thuringiensis* subspecies *israelensis* Strain SUM 6218 solids, spores and insecticidal toxins is registered by Summit Chemical Co. (SUM 6218 Primary Powder; EPA Reg. No. 6218-83).

Manufacturing Process:

Beginning with B.t.i. Primary Powder with a potency of 7,000 ITU per milligram of powder, deionized water is added to create a slurry. The slurry is given a lot number, which follows the product through its completion. The slurry is mixed with granulated cork for 3 minutes. Calcium sulfate plaster is added to the slurry and cork mixture for an additional 3 minutes. The mixture is measured and placed into a 20 cavity tray and the trays are compressed and then placed on drying racks. After the product has dried completely, samples are randomly taken and tested for proper weight and dryness. Samples are then placed into water tanks and tested for proper dispersion in water of the B.t.i. The product is packaged by blister-sealing a cardboard containing the product label onto the plastic tray containing depressions for each briquet. The lot number is then stamped onto the cardboard cover and the package is placed into a corrugated cardboard carton box for sales and shipment. Each lot number is stamped on the outside of the corrugated carton. The Summit B.t.i. Briquets are like a hockey puck in shape with a hole in the middle like a small donut. They are 5 cm (2 inches) in diameter and 1 cm (1/2 inch) thick and weight 12-13 grams each.

Deficiencies: None

Discussion of Formation of Unintentional Products:

This product differs from the original Summit® Briquets / Mosquito Dunks, EPA Reg. No. 6218-47, only by use of *Bacillus thuringiensis* subsp. *israelensis*, Strain SUM-6218, as active ingredient. Other than the intended ingredients identified in this discussion and in the CSF, EPA Form 8570-4, no significant unintentional ingredients are expected to occur in this formulated end-use product and there are no chemical reaction byproducts expected to produce unintentional ingredients.

Unintentional inert ingredients may include trace amount of less than 1% respirable quartz impurity that would be bound-up in the solid matrix of the manufactured Summit B.t.i. Briquets / Mosquito Dunks and not respirable in the whole Summit B.t.i. Briquets / Mosquito Dunks. Other inert ingredient impurities may include natural plant-origin spent fermentation media and B.t.i cell-growth byproducts.

Deficiencies: None

ANALYSIS OF SAMPLES:

Summit® B.t.i. Briquets/ Mosquito Dunks® are formulated end-use products containing 10.31% *Bacillus thuringiensis* subsp. *israelensis*, Strain SUM-6218, technical- or primary powder manufacturing-use-product (MUP or MP). The MUP/MP is analyzed for presence of contaminating bacteria, injected subcutaneously into test mice, tested for β -exotoxin, and bio-assayed against *Aedes aegypti* mosquito larvae. Summit uses bioassay on *Aedes aegypti* mosquito larvae for QC assessment of the activity instead of colony forming units (CFUs), because CFUs are not correlated to mosquito larvicidal activity.

CERTIFIED LIMITS:

Summit® B.t.i. Briquets are formulated using balances with an accuracy of ten grams with an industrial batch size of up to 1000 lbs. Summit certifies the limits of inert and active ingredients in the Confidential Statement of Formula.

ENFORCEMENT ANALYTICAL METHOD:

The registrant states that the method to determine the content of *Bacillus thuringiensis* subsp. *israelensis*, strain SUM-6218 is on file for the registered product SUM-6218 Primary Powder (EPA Reg. No. 6218-83).

Deficiencies: None

PHYSICAL AND CHEMICAL CHARACTERISTICS:

Methods: Methods for determining the applicable physical and chemical characteristics of Summit B.t.i. Briquets are given in Table 2.

Results: The physical/chemical characteristics of Summit B.t.i. Briquets are provided in Table 2.

TABLE 2. Physical and Chemical Properties of Summit B.t.i. Briquets		
Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Not required for EP	
830.6303 Physical State	hockey puck in shape with a hole in the middle like a small donut	Visual inspection at room temperature
830.6304 Odor	Not required for EP	
830.6313 Stability	Results of a one-year storage stability will be provided.	
830.6315 Flammability	N/A, the product does not contain combustible liquids	
830.6317 Storage Stability	Storage stability study is underway. Expected to be stable for up to one year in original packaging.	Insect bioassay used to evaluate active ingredient content
830.6319 Miscibility	N/A, the product is not an emulsifiable liquid and is not to be diluted with petroleum solvents.	
830.6320 Corrosion Characteristics	Study is underway. Expected to be non-corrosive in original packaging.	Visual inspection of package during storage stability study
830.7000 pH	N/A, the product is a solid not dispersible in water	
830.7050 UV/Visible Absorption	N/A, photochemical degradation is not expected	
830.7100 Viscosity	N/A, product is a solid	
830.7200 Melting Range	Not required for EP	
830.7220 Boiling Range	Not required for EP	
830.7300 Density/Relative Density/Bulk Density	1.024 gram/cubic centimeter	Hydrostatic displacement
830.7370 Dissociation Constant in Water	Not required for EP	
830.7550 Partition Coefficient	Not required for EP	
830.7840 Water Solubility	Not required for EP	
830.7950 Vapor Pressure	Not required for EP	

Deficiencies: None.

Waiver Request for Acute Oral Toxicity Study

A data waiver is requested for the following microbial pesticide EPA, OPPTS / OCSPP Guideline data requirement: 870.1100; Acute Oral Toxicity for Summit B.t.i. Briquets / Mosquito Dunks. This product differs from the original Summit B.t.i. / Briquets / Mosquito Dunks, EPA Reg. No. 6218-47, only by use of *Bacillus thuringiensis* subsp. *israelensis*, strain SUM-6218, as active ingredient.

B) The data waiver rationale for this waiver request also includes the following:

Acute oral toxicity of the active ingredient (AI) *Bacillus thuringiensis* subsp. *israelensis*, Strain SUM-6218, MP has been reviewed by the Agency and found ACCEPTABLE. Therefore, the active ingredient is not expected to cause toxicity or other adverse effects.

C) The inert Ingredients of Summit B.t.i. Briquets / Mosquito Dunks are all on EPA List 4A, Minimal Risk Inert Ingredients. Therefore, this product contains no inert ingredients expected to have oral toxicity or other adverse effects.

D) Summit® B.t.i. Briquets / Mosquito Dunks were first EPA registered in 1982 and in 33 years of production and sales there have been no reported incidents of oral toxicity or other adverse effects.

Waiver Request for Acute Dermal Toxicity Study

A) Acute dermal toxicity of the active ingredient (AI) *Bacillus thuringiensis* subsp. *israelensis*, Strain SUM-6218, MP has been done and reviewed by the Agency.

B) The inert ingredients of Summit B.t.i. / Briquets / Mosquito Dunks (See CSF, EPA Form 8570-4) are all on EPA List 4A, Minimal Risk Inert Ingredients. Therefore, this product contains no inert ingredients expected to have acute dermal toxicity or any adverse effects.

C) Summit B.t.i. Briquets / Mosquito Dunks was first EPA registered in 1982 and in 33 years of production and sales there have been no reported incidents of acute dermal toxicity or other adverse effects.

D) On the label for Summit B.t.i. Briquets / Mosquito Dunks, under PRECAUTIONARY STATEMENTS: Hazards to Humans: it states the following: "Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."

Waiver Request for Acute Inhalation Toxicity Study

The data waiver rationale for this waiver request also includes the following:

A) Acute inhalation toxicity of the active ingredient (AI) *Bacillus thuringiensis* subsp. *israelensis*, Strain SUM-6218, MP has been done and reviewed by the Agency.

B) The inert ingredients of Summit Briquets / Mosquito Dunks are all on EPA List 4A, Minimal Risk Inert Ingredients. Therefore, this product contains no inert ingredients expected to have inhalation toxicity or adverse effects.

C) Summit B.t.i. Briquets / Mosquito Dunks are 5 cm (2 inches) In diameter and 1 V* cm (1/2 inch) thick. Therefore, being of that size the entire object is not respirable.

D) Summit B.t.i. Briquets / Mosquito Dunks were first EPA registered in 1982 and in 33 years of production and sales, there have been no reported incidents of acute inhalation toxicity or other adverse effects.

E) The label PRECAUTIONARY STATEMENTS, Hazards to Humans, also states: "Avoid breathing dust."

Waiver Request for Primary Eye Irritation Study

The rationale for this waiver request also includes the following:

A) Acute eye irritation testing of the active ingredient (AI) *Bacillus thuringiensis* subsp. *israelensis*, strain UM-6218, MP was done and reviewed by the Agency.

B) The inert Ingredients of Summit B.t.i. Briquets / Mosquito Dunks are all on EPA List 4A, Minimal Risk Inert Ingredients. Therefore, this product contains no inert ingredients expected to cause acute eye irritation or other adverse effects.

C) Summit B.t.i. Briquets / Mosquito Dunks are 5 cm (2 inches) in diameter and 1 V* cm (1/2 inch) thick. Therefore, being of that size, the entire objects are too large to easily fit into human eyes.

D) Summit B.t.i. / Briquets / Mosquito Dunks were first EPA registered in 1982 and in 33 years of production and sales there have been no reported incidents of acute eye irritation or other adverse effects.

E) Under FIRST AID on the product label, there is the following statement: If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

The label PRECAUTIONARY STATEMENTS, Hazards to Humans, also states: Causes moderate eye irritation. Avoid contact with eyes or clothing.

Waiver Request for Primary Skin Irritation Study

The data waiver rationale for this waiver request also includes the following:

A). Primary dermal irritation toxicity of the active ingredient (AI) *Bacillus thuringiensis* subsp. *israelensis*, strain SUM-6218, MP has been done and reviewed by the Agency.

B) The inert ingredients of Summit B.t.i. / Briquets / Mosquito Dunks are all on EPA List 4A, Minimal Risk Inert Ingredients. Therefore, this product contains no inert ingredients expected to cause dermal irritation or have other adverse effects.

C) Mosquito Dunks were first EPA registered in 1982 and in 33 years of production and sales there have been no reported incidents of dermal irritation or other adverse effects.

D) On the label for Summit B.t.i. Briquets / Mosquito Dunks under PRECAUTIONARY STATEMENTS: Hazardous to Humans: it states the following: avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."

Hypersensitivity Incidents

A) Hypersensitivity has not been reported for *Bacillus thuringiensis israelensis*, although it is not impossible, because of the protein nature. If it occurs and is reported or known for Summit B.t.i. Briquets / Mosquito Dunks, it will be reported to the Agency through the FIFRA 6(a)(2).

B) Summit B.t.i. Briquets / Mosquito Dunks are made with technical or manufacturing-use Summit B.t.i MP, *Bacillus thuringiensis* subsp. *israelensis*. The CSF is submitted as part of the application for registration and it contains no inert ingredients known or expected to be of allergenic nature.

CONCLUSION: ACCEPTABLE. The information provided is sufficient to support the requested waivers for testing of Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, and Dermal Sensitization for Summit B.t.i. Briquets.